AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

June 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: [Docket No.: 00B-0108]; *Federal Register*, Vol. 65, Microbiology Devices; Reclassification of Fully Automated Short - Term Incubation Cycle Antimicrobial Susceptibility Devices From Class III to Class II.

In response to the notice published March 8, 2000 in the *Federal Register*, the American Society for Microbiology (ASM) would like to comment on the recommendation of the Microbiology Devices Panel to reclassify the fully automated short – term incubation cycle antimicrobial susceptibility devices, under the Food and Drug Administration.

The American Society for Microbiology is the premier education, and scientific society dedicated to the promotion of the microbiological sciences and their application for the common good. The Society represents more than 42,000 microbiologists, including scientists in academic, industry and government institutions working in a variety of areas, including medical, applied, molecular biology and genetics, environmental and food microbiology, and public health.

The ASM applauds the FDA's initiative to address the reclassification of short – term incubation cycle devices and has the following comments. The ASM's concern is based on the documented observations that short-term incubation cycle tests do not detect antibiotic resistance in selected organisms. Specifically, Staphylococcus and Enterococcus with low level resistance to vancomycin are misclassified as susceptible. This is the reason the NCCLS documents (M2, M7, and M100) have recommended incubation for a full 24 hours for these tests. Additionally, Enterobacteriaceae producing extended spectrum beta-lactamases have proved to be problematic for these systems.

If the FDA decides to approve this reclassification, then it should be specifically stated that no susceptibility test will be approved unless the manufacturer can demonstrate equivalence with overnight susceptibility tests, particularly those tests that have been found to require extended incubation.

The ASM is pleased to have the opportunity to provide comments on the Microbiology Device Panel's decision to reclassify fully automated short – term incubation cycle antimicrobial susceptibility devices from class III to class II. The ASM believes that it will assist manufacturers and the FDA and thus provide an improved process for health care providers.

00B-0108

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Sincerely,

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Chair, Public and Scientific
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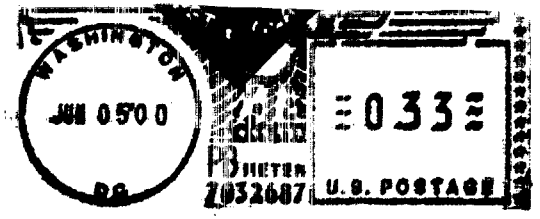
Patrick Murray, Ph.D.
Chair, Laboratory Practices
Committee

Ronald Zabransky, Ph.D.
Chair, Subcommittee on Microbiology
Devices



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